Decision Memo for Lipid and Blood Glucose Testing (Modification of Code List to Implement Screening Benefit Added by Medicare Modernization Act (MMA) (CAG-00266N)

Decision Summary

CMS has determined that ICD-9-CM diagnosis codes V81.0, V81.1 and V81.2, Special screening for cardiovascular diseases, and V77.1, Special screening for diabetes mellitus, should be removed from the list of codes that are not covered by Medicare for clinical diagnostic laboratory services. In addition, codes V81.0, V81.1 and V81.2 are appropriately added to the list of covered diagnosis codes for lipid tests 80061, 82465, 83718 and 84478 under the cardiovascular screening benefit (section 1861(xx)). Code V77.1 is appropriately added to the list of covered diagnoses for procedure code 82947, which is part of the blood glucose NCD, as diabetic screening (section 1861(yy)).

Back to Top

Decision Memo

This coding analysis does not constitute a national coverage determination (NCD). It states the intent of the Centers for Medicare & Medicaid Services (CMS) to issue a change to the list of ICD-9-CM Codes Covered that are linked to one of the negotiated laboratory NCDs. This decision will be announced in an upcoming recurring update notification in accordance with CMS Pub 100-4, Chapter 16, section 120.2 and will become effective as of the date listed in the transmittal that announces the revision.

To: Administrative File: CAG- 00266L Lipid and Blood Glucose Testing (Modification of Code List to Implement Screening Benefits Added by Medicare Modernization Act (MMA))

From:

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Re: Coding Analyses for Lipid and Blood Glucose Testing for Screening Purposes
Date: November 29, 2004

I. Decision

CMS has determined that ICD-9-CM diagnosis codes V81.0, V81.1 and V81.2, Special screening for cardiovascular diseases, and V77.1, Special screening for diabetes mellitus, should be removed from the list of codes that are not covered by Medicare for clinical diagnostic laboratory services. In addition, codes V81.0, V81.1 and V81.2 are appropriately added to the list of covered diagnosis codes for lipid tests 80061, 82465, 83718 and 84478 under the cardiovascular screening benefit (section 1861(xx)). Code V77.1 is appropriately added to the list of covered diagnoses for procedure code 82947, which is part of the blood glucose NCD, as diabetic screening (section 1861(yy)).

II. Background

On October 25, 2004 CMS began a coding analysis for expansion of the “ICD-9-CM Covered Codes” list for the lipid and blood glucose testing NCDs. Lipoproteins are a class of heterogeneous particles of varying sizes and densities containing lipid and protein. The lipoproteins include cholesterol esters and free cholesterol, triglycerides, phospholipids and A, C, and E apoproteins. In many individuals, an elevated blood cholesterol level constitutes an increased risk of developing coronary artery disease. Blood levels of total and various fractions of cholesterol are useful in assessing and monitoring treatment for that risk in patients with cardiovascular and related diseases.

Quantitative blood glucose testing measures the amount of glucose in the blood. In patients with untreated diabetes, the amount of glucose contained in the blood is significantly higher (hyperglycemic) than the general population. Quantitative blood glucose testing is an appropriate means of screening for diabetes.

III.History of Medicare Coverage

We have historically interpreted the Medicare routine service exclusion in the law (section 1862(a)(7)) to significantly limit the coverage of preventive services to Medicare beneficiaries. In December 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) (Pub. L. 108-173). The MMA, among many other things, added two new screening benefits for Medicare beneficiaries. Section 612 provided for Medicare coverage of cardiovascular screening blood tests for the early detection of cardiovascular disease or abnormalities associated with an elevated risk for that disease. Section 613 of the MMA provides for testing furnished to an individual to assess risk for diabetes. Both provisions become effective for services furnished on or after January 1, 2005.

On August 5, 2004, CMS issued a Notice of Proposed Rulemaking (NPRM) (69 FR 47488) outlining a plan for implementation of these new statutory benefits. In summary, the proposed implementation for lipid testing permitted coverage of measurement every 5 years of total cholesterol, high-density lipoprotein cholesterol, and triglycerides. The proposed rule further stated that laboratory tests could be furnished through a lipid panel (CPT code 80061) or individually (82465, 83718, and 84478). These laboratory tests are part of the lipid NCD developed under the negotiated rulemaking authority. The NPRM further proposed that ICD-9 -CM diagnosis codes V81.0, V81.1 or V81.2 must appear on the claim to indicate the tests were being furnished under the screening benefit.

The proposed rule included several tests for diabetes screening at various frequencies depending on the risk factors displayed by the patient. The types of testing proposed as diabetes screening included quantitative blood glucose (CPT 82947), which is presently included in the blood glucose NCD. The other glucose testing procedures proposed as screening are not presently included in the NCD for blood glucose and thus are not discussed in this coding analysis. The ICD-9-CM diagnosis code proposed for screening was V77.1. Following a 60-day public comment period, CMS issued a final rule on November 15, 2004 (69 FR 66285). The final rule adopted the cardiovascular screening benefits as proposed relative to the laboratory NCDs. Although changes were made in the diabetes screening benefit, they did not affect the blood glucose NCD.

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. These NCDs included lipid and blood glucose testing. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the laboratory NCDs, CMS determined that specific tests were reasonable and necessary for certain medical indications. These decisions were evidence-based, relying on scientific literature reviewed by the negotiating committee. The NCDs contain a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled “ICD-9-CM Codes Covered by Medicare,” and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled “ICD-9-CM Codes Denied,” and lists diagnosis codes that are never covered by Medicare. The third list is entitled “ICD-9-CM Codes that do not Support Medical Necessity,” and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary. We determined in the lipid and blood glucose testing NCDs that any ICD-9-CM code not listed in either of the ICD-9-CM covered or not covered sections would be categorized into this group that does not support medical necessity.

IV. Timeline of Recent Activities

On August 5, 2004, CMS issued an NPRM (69 FR 47488) proposing a methodology to implement the cardiovascular and diabetes screening benefits under the MMA. This proposed rule provided for a 60-day public comment period. Several of the laboratory tests proposed for coverage under the screening benefits were subject to NCDs. Without modification, the edits implementing the NCDs would result in denial of the screening benefit services.

On October 25, 2004, after analysis of the public comments received on the NPRM, CMS open an internally generated coding analysis item regarding cardiovascular and diabetes screening services related to the lipid and blood glucose NCDs. We posted a tracking sheet to the Internet site (http://cms.hhs.gov/mcd/viewtrackingsheet.asp?id=140), soliciting public comment for 30 days on the appropriateness of adding diagnosis codes V81.0, V81.1 and V81.2 to the list of covered diagnoses for procedure codes 80061, 82465, 83718, and 84478 in the lipid NCD. We also proposed adding diagnosis code V77.1 to the list of covered diagnoses for procedure code 82947 in the blood glucose NCD. In addition, we proposed removing diagnosis codes V81.0, V81.1, V81.2, and V77.1 from the list of ICD-9-CM Codes Not Covered by Medicare. By the end of the public comment period, November 25, 2004, we had received two public comments.

One commenter expressed concern that adding the screening diagnoses to the lipid and blood glucose NCDs may confuse readers by implying that the codes could be covered all the time when in fact they are subject to frequency limitations. However, since every ICD-9-CM code is on one of the three lists, failure to include the codes on the covered list would result in inclusion on the list that “Does Not Support Medical Necessity.” Codes from this list are denied unless they are accompanied by medical documentation. We will however, include a reference to the screening frequency limitations in the NCD narrative indications section.

A second commenter requested that screening tests be given unique HCPCS codes, as currently is the case for PSA and fecal occult blood screening tests. In this way modification of the NCD covered codes list would not be required. A similar comment was made during the public comment period on the proposed rule and a detailed response is addressed in the final rule. In brief, several major referral laboratories have frequently complained about use of unique HCPCS codes for screening tests and requested coding by the existing CPT codes for the test similarly to other third party payer treatment. In accordance with HIPPA’s objective to promote consistency in electronic claims processing methods among insurers, we are using the existing CPT codes for the subject tests to identify them regardless of whether they are used for screening or diagnostic purposes.

V. General Methodological Principles

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage. Thus, all of the codes in the covered code list must flow from the narrative indications of the NCD. We reiterated this position in the November 23, 2001 final rule (66 FR 58795) and in subsequent implementing instructions (Program Memorandum AB-02-110).

VI. CMS Analysis

Generally, our coding analyses center around the question of whether a code flows from the narrative indications of the NCD. However, in this case, the statute has modified the Medicare program benefit package to provide for coverage of services heretofore not covered by Medicare. These services are screening cardiovascular services and screening diabetes services. The NCDs implementing these new statutory benefits were announced in the *Federal Register* and are being placed in the NCD Manual at sections 210.4 and 210.5. Since these changes are subsequent to the negotiations, it is necessary to adjust the clinical diagnostic laboratory NCD coding lists to account for these new benefits. Similarly, the coding lists must be adjusted to remove these screening diagnoses from general non-coverage.

The substantive issues as to which codes are appropriate to implement the screening benefits have been addresses in the final rule published November 15, 2004 (69 FR 66285). This Coding Analysis for Laboratories merely adopts the substance of this final rule. Additional codes for screening purposes under these statutory benefits may be requested under the NCD process. Should future changes impact upon the NCDs corresponding changes will be made to the code lists as necessary to ensure consistency.

Back to Top